



1029181

August 26, 2016

Documents Processing Desk – 6(a)(2)
U.S. Environmental Protection Agency
Office of Pesticides Programs
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

RE: FIFRA Section 6(a)(2) Report
Ceva Animal Health, LLC – Company Number 83399

Dear Sir/Madam:

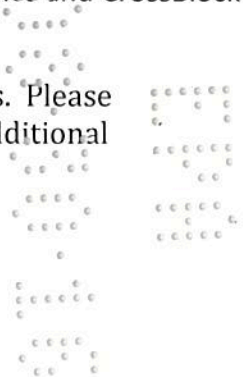
Ceva Animal Health, LLC is submitting the 2nd Quarter (Apr-Jun) 2016 aggregate reports for the following product registrations:

- (SVP-7) Vectra 3D and SimpleGuard3, EPA Registration No. 83399-6; also sub-registered as First Shield Trio, EPA Reg. No. 83399-6-85581
- (SVP-8) Vectra for Cats, Vectra for Cats and Kittens, and SimpleGuard for Cats and Kittens, EPA Reg. No. 83399-9; also sub-registered as First Shield for Cats, EPA Reg. No. 83399-9-85581
- (SVP-9) Vectra for Dogs and Puppies, EPA Reg. No. 83399-10; also sub-registered as First Shield Dog and Puppy, EPA Reg. No. 83399-10-85581
- (CAH12) Vectra Pro Flea Spray, EPA Reg. No. 83399-12
- (Imidacloprid & Pyriproxyfen Spot-on Solution for Cats) Combiva II For Cats and CrossBlock II For Cats, EPA Reg. No. 83399-16
- (Imidacloprid & Pyriproxyfen Spot-on Solution for Dogs) Combiva II For Dogs & Puppies and CrossBlock II For Dogs & Puppies, EPA Reg. No. 83399-17

We trust this information satisfies EPA FIFRA Section 6(a)(2) reporting requirements. Please contact me by phone at 913-754-7668 or by e-mail at alicia.henk@ceva.com if any additional information is required.

Sincerely,


Alicia Henk
Director,
Development and Pharmaceutical Regulatory Affairs





CC: California Department of Pesticide Registrations
Adverse Effects Reporting
1001 I Street
P.O. Box 4015
Sacramento, CA 95812-4015

New York Department of Environmental Conservation
Office of Pesticides
625 Broadway
Albany, NY 12233-4500



FIFRA 6(a)(2) Adverse Effects Reporting Aggregate Report Form

FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-6

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Product Name: Vectra 3D

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-001

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|----------------|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 370 | 24 | 1 | 1 ^A | 1 | 41 | 301 |

^A Case Details:

2016-US-00948: On 13 Apr 16, Middie (canine, 8yr, 8.5lb, spayed, female, Shih Tzu) in good condition, with a history of a heart murmur, chewing and itching, received Vectra 3D 5-10lb (Lot unknown, HP) one tube, topically, by the owner, for the prevention of fleas and ticks. This was the first known application. A Depo Medrol injection was administered the same day. The owner administers Children's Benadryl Liquid every night.

On 14 Apr 16, one day post application, the dog could not sleep, could not defecate and had a jerking motion in the back legs. Benadryl Liquid was administered. The dog became polydipsic.

On 15 Apr 16, two days post application, the dog was examined by a veterinarian. The owner reported the dog acting "crazy", shaking, shaking her legs, trying to vomit, running and then sitting and kicking (paraesthesia), anorexia and adipsia. The physical examination showed harsh lung sounds with tracheal auscultation, bilateral grade five of six heart murmur with palpable thrill, harsh lung sounds in all fields. The dog was diagnosed with a heart murmur, tracheobronchitis and an allergic reaction to Vectra 3D. An injection of Diphenhydramine and Depo Medrol were administered. Drontal Plus and Albuterol Sulfate 1.7mL by mouth as needed was prescribed.

On 20 Apr 16, one week post application, the owner noticed the right eye had green discharge. A human eye drop was administered.

On 26 Apr 16, two weeks post application, the dog has a swollen stomach, is not defecating appropriately. The owner administered mineral oil.

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On 28 Apr 16, fifteen days post application, the dog was re-examined by a veterinarian. The owner reported the dog was lethargic, abnormal breathing, matting eyes, and possible fluid buildup. The physical examination showed exophthalmoses both eyes, stressed facial expression, mucoid ocular discharge both eyes with mild corneal edema in the right eye. Chest auscultation revealed expiratory dyspnea, panting, air movement in the ventral lung fields. A radiograph was preformed. The cardiac silhouette was not visible due to congestion, caudodorsal lung fields clear on lateral, but that's it. DorsoVentral performed as patient couldn't tolerate VentroDorsal. The cardiac silhouette still not visible/well defined due to fluid. The dog was diagnosed with congestive heart failure. An injection of Lasix was administered. Lasix-Furosemide was prescribed. The owner was advised that it is imperative that the dog receives the medication, but she may not respond. The owner stated she understood.

On 02 May 16, three weeks post application, the owner started administering the Lasix. The owner administered 0.4mL three times. The dog was using the restroom, but still anorexic for five days. The owner administered sugar and honey.

On 04 May 16, three weeks post application, the owner called the clinic and reported the dog died. Permethrins can cause paresthesia or a tingling sensation that some pets find disturbing which may have contributed to the initial symptoms. However, due to the animal's underlying condition, it is difficult to determine the role the product played in the causality of the additional clinical signs that were reported on 20 Apr 16 to present. This case is medically closed.

This case became serious upon medical records received 11 May 16 with info of the death of the animal.



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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-6

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Product Name: SimpleGuard 3

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-002

| | Exposure Types and Severity Category Designations | | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|-----|
| Total Incidents | H-D | H-E | D-A | D-B | D-C | D-D | D-E |
| 56 | 0 | 0 | 0 | 0 | 3 | 53 | 0 |

56
0
0
0
0
3
53
0

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FIFRA 6 (a)(2) Aggregate Adverse Effect Information Submission Form

Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-6-85581

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Product Name: First Shield Trio

Active Ingredients: Dinotefuran, Pyriproxyfen, Permethrin

-003

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|----------------|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 72 | 3 | 0 | 1 ^A | 2 | 8 | 58 |

^A Case Details:

2016-US-002152: On 07 Jun 16, Benji (dog, 18 wks, 7.2lb, M/I, Shih Tzu) in good condition with a history of pruritus, skin rash, and fleas had FirstShield Trio 5-10lb (lot and pkg size unknown) applied topically by the pet owner for the treatment of fleas. It is unknown if the pet has had the product previously. It is unknown if any concomitant products were administered.

On 07 Jun 16, an unknown time post application the dog was bathed with a pet shampoo. It is unknown if the pet was exhibiting any clinical signs at this point.

On 08 Jun 16, one day post application, the dog developed emesis, dark yellow urine, lethargy, anorexia, weight loss (down to 6.8lb), and adipsia. The dog was seen by the attending veterinarian. A parvovirus snap test was performed, and was negative. The dog was treated with Lactated Ringers (70ml/SQ), Cerenia (0.3ml/SQ), dispensed a gastrointestinal HE puppy food and I/D food. On 08 Jun 16, after the dog was treated at the clinic, the dog continued to exhibit the clinical signs, so the owner contacted the veterinarian. The veterinarian recommended bathing the dog in Dawn dish soap, and the proper dosing of Benadryl that was started on an unknown date and time post application of the product. The veterinarian also recommended using syrup when the dog is not eating.

On 09 Jun 16, two days post application, the clinical signs persisted. The attending veterinarian recommended trying warm broth to help with the anorexia. The veterinarian recommended that if the dog is not eating by the next day that the dog be rechecked.

2016-US-002152

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On 10 Jun 16, three days post application, the dog was rechecked by the veterinarian. The dog had continued to lose weight (down to 6.4lb), and now had diarrhea. On physical exam the dog had yellow discharge from both eyes, pale mucus membranes, 7% dehydration, icteric sclera, integumentary, and mucus membranes, and a grade IV/VI heart murmur. Blood work was performed and the results were as follows: Elevated WBC (25.6), ALKP (673), ALT (240), Amylase (2500), CREA (3.7), PHOS (16.1), TBIL (9.1), BUN (130), and Decreased RBC count (4.79), and HCT (32.8). A fecal test was performed and was positive for roundworms and tapeworms. A 1.5 foot tape worm was pulled from the dog's rectum. The dog was hospitalized for treatment. An IV catheter was placed to deliver IV fluids (12ml/HR). The dog was also treated with Cestex (18.75mg/PO). An unknown time after treatment the pet showed some improvement, but then quickly went downhill. The owner elected to euthanize the dog.

On 10 Jun 16, three days post application, the dog was euthanized. A necropsy was not performed. Vomiting is a labeled even with the product if orally ingested. However, the product is unlikely the cause to the more serious systemic events such as liver and kidney failure that occurred in this case. This case is medically closed.



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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-9

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Product Name: Vectra for Cats/ Vectra for Cats and Kittens

Active Ingredients: Dinotefuran, Pyriproxyfen

-004

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|----------------|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 22 | 0 | 0 | 2 ^A | 0 | 1 | 19 |

^A Case Details:

2016-US-00841: On 04 Apr 16, Molly (feline, 12yr, unknown weight, spayed, female, Domestic Longhair) in unknown medical condition, with unknown previous medical history, received Vectra for Cats over 9lb (Lot unknown, 3pk) one tube, topically, by the owner, for the prevention of fleas. It is unknown how many times this product has been used previously. A dog in the household was treated at the same time with Vectra 3D 56-95lb.

On 04 Apr 16, within eleven hours post application, the cat exhibited muscle tremors, seizures, urinating, and bulging eyes. The cat was examined by a veterinarian. The physical examination showed muscle tremors, clonic tonic type seizure, foaming at the mouth, dilated pupils, and hyperesthesia. No treatment was performed. The owner elected euthanasia.

On 04 Apr 16, within twelve hours post application the cat was euthanized. This is not a typical event that is seen with the use of the feline product. It is more likely that the cat ingested some of the permethrin from the dog product after the housemate was treated. Also, the veterinarian's assessment was suspected permethrin toxicity. This case is medically closed.

2016-US-00998: On 11 Apr 16, Roxy (7yr, 10lb, F/S, DSH) in good condition with no previous medical history had Vectra for Cats and Kittens over 9lbs (lot 1736300, 3pk) applied topically by the pet owner for the prevention of fleas. The product has been applied previous months with no issues. There were no concomitant products administered.

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On 12 Apr 16, twenty four hours post application the cat developed hypersalivation, and drooling. On 13 Apr 16, forty-eight hours post application the cat developed agitation, convulsions, coughing, and then passed away after running through the house.

On 13 Apr 16, the cause of the death was unknown as no necropsy was performed. This is not a typical event with this product. Since a necropsy was not performed, it is unknown what role, if any, the product played in the event. Case is medically closed.



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Product Name: SimpleGuard for Cats

Active Ingredients: Dinotefuran, Pyriproxyfen

-005

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 6 | 0 | 0 | 0 | 0 | 1 | 5 |

SimpleGuard

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Active Ingredients: Dinotefuran, Pyriproxyfen

-006

| | Exposure Types and Severity Category Designations | | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|-----|
| Total Incidents | H-D | H-E | D-A | D-B | D-C | D-D | D-E |
| 7 | 1 | 0 | 0 | 1 | 2 | 3 | 0 |

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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-10

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Product Name: Vectra for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

-007

| | Exposure Types and Severity Category Designations | | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|-----|
| Total Incidents | H-D | H-E | D-A | D-B | D-C | D-D | D-E |
| 6 | 2 | 0 | 0 | 0 | 0 | 4 | 0 |

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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-10-85581

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Product Name: First Shield for Dogs and Puppies

Active Ingredients: Dinotefuran, Pyriproxyfen

- 008

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 5 | 1 | 0 | 0 | 0 | 0 | 4 |



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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-12

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Product Name: Vectra Pro Flea Spray

Active Ingredients: Dinotefuran

-009

| Total Incidents | Exposure Types and Severity Category Designations | | | | | | |
|-----------------|---|-----|----------------|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D | D-E |
| 2 | 0 | 0 | 1 ^A | 0 | 0 | 1 | 0 |

^A Case Details:

2015-US-001338: On 05 May 16, Gray (approx. 8 weeks, approx. 2lb, M/I, DSH) in fair condition with a severe flea infestation was exposed to Vectra Pro Flea Spray (Lot 1603500, via application to a towel in their kennel) for the treatment of fleas. The product was administered by the office manager, and it is unknown how many sprays were applied to the towel. This was the first time the product was administered. On 07 May 16, the kitten was also treated with Ivermectin (0.1 mL in each ear for ear mites).

On 08 May 16, three days post application, and one day post application of the Ivermectin, the kitten developed lethargy as if sedated, and mild tremors. There were no diagnostic tests performed. The kitten was treated with a bath in Dawn dish soap, warm SQ fluids, and external thermoregulation. On 09 May 16, one day post application, the kitten was administered more warm SQ fluids. A snap test for FELV/FIV was performed and was negative. On 11 May 16, six days post exposure to the product and four days post application of the Ivermectin, Gray continued to decline and was not expected to survive.

On 12 May 16, seven days post exposure to the product and five days post application of the Ivermectin, the kitten passed away. This kitten was exposed to multiple products concurrently. This makes it impossible to determine what role, if any, the product played in this event. Case is medically closed.

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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-16

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Product Name: Combiva II For Cats

Active Ingredients: Imidacloprid, Pyriproxyfen

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |



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Period Covered: 2nd Quarter (Apr-Jun) 2016

Submission Date: 26 Aug 16

EPA Reg. No.: 83399-16

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Product Name: CrossBlock II For Cats

Active Ingredients: Imidacloprid, Pyriproxyfen

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |



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Active Ingredients: Imidacloprid, Pyriproxyfen

| | Exposure Types and Severity Category Designations | | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|-----|
| Total Incidents | H-D | H-E | D-A | D-B | D-C | D-D | D-E |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

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Period Covered: 2nd Quarter (Apr-Jun) 2016

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EPA Reg. No.: 83399-17

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Product Name: CrossBlock II For Dogs & Puppies

Active Ingredients: Imidacloprid, Pyriproxyfen

| Total Incidents | Exposure Types and Severity Category Designations | | | | | |
|-----------------|---|-----|-----|-----|-----|-----|
| | H-D | H-E | D-A | D-B | D-C | D-D |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 |

11/11/16

11/11/16